

NOTE: Still open, last updated 7/12/01.

October 29, 1998

**OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)**

PROGRAM ANNOUNCEMENT



Investigator-Initiated Research on Patient-Centered Outcomes

1. Purpose. The Veterans Health Administration (VHA) is focusing major resources and energy to improve the quality of the health care it provides and to create improvements that are measurable, rapid and sustainable. With the inauguration of the Quality Enhancement Research Initiative (QUERI) in early 1998, special emphasis has been placed on improving the quality of care in ten clinical areas that are prevalent in VA: chronic heart failure, ischemic heart disease, diabetes, prostate disease, stroke, substance abuse, mental health (depression and schizophrenia), spinal cord injuries, HIV/AIDS, and cancer. For each of these areas, QUERI will identify gaps in science, practice, and information systems, and will develop and evaluate methods for translating evidence of clinical effectiveness into practice. Additional information about QUERI is available on the VA web page at <http://www.va.gov/resdev>.

2. Synopsis. This Program Announcement invites eligible VA investigators (see paragraph 7a) to propose Investigator-Initiated Research (IIR) projects that will define and assess patients' expectations for VA health services with respect to the ten QUERI conditions. Projects may request up to two years and total cost of up to \$400,000; however, HSR&D is especially interested in projects that can demonstrate results in a shorter time frame. For the initial round of review, a brief planning letter (Attachment A) must be received by December 10, 1998, and full proposals must be received by February 5, 1999. The first proposal review opportunity will be March, 1999, with the earliest possible funding date of April 1999. Thereafter, projects will require a Letter of Intent consistent with regular IIR policy, and proposal due dates are May 1 and November 1, until further notice.

3. Patient-Centered Care. Patient-centered health care addresses patients' needs and concerns, as defined by the patient. Patient-centered medicine is

contrasted with illness-centered medicine which focuses on the technical aspects of quality health care. Patient-centered care focuses on both the subjective and objective dimensions of health care quality as experienced by the patient and their family, in terms of their perceptions of illness and well-being and in their encounters with the VA health care system and providers (for further description of patient-centered care and a short bibliography see R&D Information Letter, IL 12-97-012, available through your local R&D office or on the internet at <http://www.va.gov/resdev>).

4. Research Focus. While a growing number of valid, reliable and clinically relevant measures exist to measure generic and disease-specific patient outcomes, more research is needed addressing disease-specific treatment outcomes *important to patients*. What are the outcomes that diabetic, spinal cord injured, stroke patients, etc. value? How can these outcomes, once identified, best be measured, tracked and communicated back to clinicians? Patient-centered outcomes necessarily employ subjective as well as objective measures. The proposed studies are expected to produce new knowledge for improving the quality of, and patient satisfaction with, VA health services. The goal of this special solicitation is to define and assess patients' expectations for VA health services and to better understand the sources of patients' expectations with respect to the ten QUERI conditions.

Proposals that rely on multiple methods, both quantitative and qualitative, are strongly encouraged. Proposals that employ rigorous qualitative methods exclusively may also be appropriate. Studies must target one or more of the initial QUERI clinical conditions (see paragraph 1). Relevant subgroup analysis within targeted conditions is encouraged. *Studies of patient-centered care that do not focus on outcomes, or that concern clinical conditions other than the ten QUERI conditions should be submitted through HSR&D's regular Investigator Initiated Research (IIR) program. Investigators interested in other aspects of the ten QUERI conditions should see pertinent solicitations posted on VA's web page, at <http://www.va.gov/resdev/hsr-sols.htm>.*

5. Sample Research Issues. With respect to one or more of the ten QUERI conditions identified in paragraph 1, examples of suitable research questions include, but are not limited to the following:

a. What are the outcomes, issues and concerns (e.g., psychosocial, treatment preferences, symptom relief, quality of life, advance care planning) that patients identify as important? How do these differ by patient characteristics (e.g., age, race/ethnicity, gender, socioeconomic status, health status, military cohort, phase of treatment)? What outcomes, issues and concerns do family members and patients' caregivers identify as important?

b. What are patients' expectations and preferences for treatment? Do their preferences or expectations vary by stage of disease, treatment phase, or patient

characteristics? Are individuals' preferences stable? What are the best methods for measuring patients' expectations and preferences?

c. How do patients' expectations and preferences for medical treatment and outcomes differ from those of the clinicians treating them? If expectations and preferences differ, how might these differences be addressed?

d. How do patients' expectations and preferences for medical treatment and clinical outcomes differ from the actual care received and the outcomes achieved? If expectations and actual practice differ, how might we address these differences?

e. Are the concerns of patients adequately addressed in the content and scoring of existing disease-specific and generic outcome measures (e.g., patient satisfaction, quality of life, functional status)? How do patient characteristics affect their willingness to complete existing specific outcome measures? How does the method of data collection affect response rates?

f. Are there opportunities and methods (e.g., patient education, self-efficacy) for improving patient, and if applicable provider, adherence to established therapies and the reduction in unhealthy behaviors? What are the appropriate methods for measuring patient compliance?

g. Are there gaps in patient knowledge and understanding of their clinical condition, its treatment, or patient health behaviors necessary to either maintain or improve desired outcomes or minimize to adverse health consequences?

h. If applicable, what do patients identify as important end-of-life issues and concerns (e.g., familial, emotional, spiritual, physical, economic)? How do patients define a "good death?" How do family/care providers define a "good death" for these patients? How do patients' expectations and preferences for end-of-life care differ from clinicians treating them, and family/careproviders? If expectations and preferences differ, how might we address these differences?

6. Research Methods. All HSR&D studies are expected to use research designs and methods that maximize the validity, reliability, generalizability, and usefulness of findings. While the research needs to be grounded in the realities of VA practice and address real world information needs, it also needs to have a clear theoretical framework, demonstrate familiarity with the pertinent literature, and employ a data collection and analysis strategy that will yield valid conclusions. The multidisciplinary nature of health services research needs to be evident in the formulation of the research questions, and the methodological approach may draw from any, or several, discipline(s). Study teams should generally include individuals with experience and expertise in clinical and non-clinical fields, including pertinent social scientists and research methodologists. The research needs to be designed to maximize the eventual application of findings and conclusions.

In general, priority will be given to explanatory studies (over descriptive studies) and studies designed to maximize the generalizability of findings, at least within VA. Studies that employ both qualitative and quantitative methods are encouraged. Good qualitative studies will employ a conceptual framework and pose one or more well-defined research question(s). Investigators who choose to employ qualitative methods are encouraged to consult appropriate texts (see IL 12-97-012), and involve qualitative methodologists in the design and conduct of their research protocols. Investigators are also cautioned that qualitative methods often result in a multitude of data and require a well-defined data management and data analysis plan.

Studies responsive to this solicitation are expected to meet the above general criteria. They should add new knowledge based on an appropriate conceptual framework and appropriate research design and methods, including adequate controls and statistical power. Applicants are advised to pay particular attention to conceptual and methodological issues that make research in patient-centered outcomes especially challenging.

7. Application Process.

a. Eligibility. Investigators who hold a VA appointment of at least 5/8 time are eligible to apply for research support. Co-investigators, consultants, and support staff may be non-VA employees. Refer questions about eligibility to Robert Small at 202.273.8256 or robert.small@mail.va.gov.

b. Planning Letter. A planning letter is the first step in preparing a proposal responsive to this announcement. It will be used only for administrative purposes (for format, see attachment A). The usual Letter of Intent (LOI) process required for HSR&D Investigator-Initiated Research projects, whereby a detailed description of the project must be approved prior to submitting a full proposal, **does not apply** to the initial round of review for this solicitation. Planning letters are due at the address listed in paragraph 11 ("Mailing Address"), by the close of business on December 10, 1998. Facsimile and electronic mail copies will be accepted; address these to John Francis, HSR&D Service, at FAX number 202.273.9007 or john.francis@mail.va.gov.

c. Proposal Preparation and Submission. For detailed instructions regarding preparation and submission of a full proposal, and general review criteria, applicants should refer to HSR&D's "Instructions for Preparing Investigator-Initiated Research Proposals" (available at all VA research offices and on the VA research home page at <http://www.va.gov/resdev>).

d. Review Schedule. Proposals received by February 5, 1999 will be reviewed at the Scientific Review and Evaluation Board subcommittee meeting in March 1999. Subsequently, and until further notice, proposals responsive to this announcement, based on an approved LOI, will be reviewed at regularly

scheduled meetings of the Board, along with other IIR projects. Proposals received by May 1 are reviewed in June; proposals received by Nov. 1 are reviewed in January.

8. Review Criteria. IIR review is rigorous and standards very high; both scientific merit and expected contribution to improving VA health services are considered. Any design and any method(s) consistent with paragraph 6 are acceptable. Investigators are expected to develop and describe their research plan completely and in detail. Proposals recommended for approval will be considered for funding.

9. Funding. Studies submitted in response to this solicitation may not exceed two years or total costs of \$400,000. Both short-term and long-term projects may be proposed, but HSR&D is particularly interested in projects that can demonstrate results in the shortest possible time. **Note:** For projects that require more than two years, investigators are *strongly encouraged* to identify major milestones or project components for which interim results can be reported and published. In planning project budgets, applicants are reminded to adhere to R&D guidelines regarding allowable use of research funds for specific items. HSR&D expects to fund the first projects under this program in April 1999.

10. Coordination with QUERI. Principal investigators will be expected to submit regular annual progress reports and requested updates to the Director, HSR&D, who will provide these to the appropriate QUERI Coordinating Center, through the Associate Director for QUERI.

11. Mailing Address. Proposals submitted under this initiative may be submitted by regular mail or Federal Express, via the ACOS for R&D and the Medical Center Director, with a letter of support signed by the Medical Center Director. Submit proposals for receipt by February 5, 1999 to:

HSR&D Service (124F)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

12. Inquiries. For further information regarding this solicitation, contact Jay A. Freedman, Ph.D., Assistant Director, Research Initiatives and Analysis, HSR&D (202.273.8246) or jay.freedman@mail.va.gov. For information about procedures and review, including eligibility for support, contact Robert Small, at (202-273-8256 or robert.small@mail.va.gov).

John R. Feussner, M.D.

Chief Research and Development Officer

**FORMAT FOR HSR&D PLANNING LETTERS
FOR PROJECTS RESPONDING TO**

Patient-Centered Outcomes

Provide a one-page letter addressed to the HSR&D Review Program Manager (124F), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC, 20420, including the following information:

1. Principal Investigator's name, affiliation, address, phone number, e-mail, and FAX number.
2. Name and affiliation of co-Principal Investigator, if applicable, and other key project participants.
3. Title and date of the solicitation to which you are responding, i.e., Patient-Centered Outcomes, October 29, 1998.
4. Proposal title.
5. Specific focus of the proposed study.
6. Major methods to be used and type(s) of analyses to be performed.
7. (Optional) Two or more scientists who are qualified to review the proposal; include name, degree, title, academic affiliation, complete address, telephone number, and e-mail address.
8. Signature of the ACOS for R&D.